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**From:** Komolprasert, Vanee [Vanee.Komolprasert@fda.hhs.gov]  
**Sent:** 4/29/2016 1:50:02 PM  
**To:** Krasnic, Toni [krasnic.toni@epa.gov]  
**CC:** Wolf, Joel [Wolf.Joel@epa.gov]; Lloyd, Tyler [Lloyd.Tyler@epa.gov]  
**Subject:** RE: Questions on PFOS \_3M notice

Thanks Toni. We surely contact you in case we have comments that need EPA info.  
Have a good weekend.  
Best,  
Vanee

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**From:** Krasnic, Toni [mailto:krasnic.toni@epa.gov]  
**Sent:** Friday, April 29, 2016 9:23 AM  
**To:** Komolprasert, Vanee  
**Cc:** Wolf, Joel; Lloyd, Tyler  
**Subject:** RE: Questions on PFOS \_3M notice

Thanks Vanee! Let's connect again before you finalize in case you receive any comments.

Thanks,

Toni Krasnic  
Existing Chemicals Branch  
EPA/OCSPP/OPPT/CCD/ECB  
WJC East, 4134D | (202) 564-0984

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**From:** Komolprasert, Vanee [mailto:Vanee.Komolprasert@fda.hhs.gov]  
**Sent:** Friday, April 29, 2016 9:06 AM  
**To:** Krasnic, Toni <krasnic.toni@epa.gov>  
**Cc:** Wolf, Joel <Wolf.Joel@epa.gov>  
**Subject:** RE: Questions on PFOS \_3M notice

Hi Toni,

FYI. The 3M Notice has been published today, available at <https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-09932.pdf>.

Vanee

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**From:** Krasnic, Toni [mailto:krasnic.toni@epa.gov]  
**Sent:** Wednesday, April 27, 2016 8:29 AM  
**To:** Komolprasert, Vanee  
**Cc:** Wolf, Joel  
**Subject:** RE: Questions on PFOS

Hi Vanee,

Thank you for the additional information on the two FCSs.

I checked with our chemist and FCS2 (CASN 92265-81-1) is not on the Toxic Substances Control Act (TSCA) Inventory. As a result, any person who intends to

manufacture (which is defined by TSCA to include import into the customs territory of the United States) this polymer must complete the TSCA Premanufacture Notice (PMN) review process prior to commencing the manufacture or import of this polymer. Additional information on the PMN process is available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

Thanks, and let me know if any other questions.

Toni Krasnic  
Existing Chemicals Branch  
EPA/OCSP/OPPT/CCD/ECB  
WJC East, 4134D | (202) 564-0984

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**From:** Komolprasert, Vanee [<mailto:Vanee.Komolprasert@fda.hhs.gov>]  
**Sent:** Tuesday, April 26, 2016 9:18 AM  
**To:** Krasnic, Toni <[krasnic.toni@epa.gov](mailto:krasnic.toni@epa.gov)>  
**Cc:** Wolf, Joel <[Wolf.Joel@epa.gov](mailto:Wolf.Joel@epa.gov)>  
**Subject:** RE: Questions on PFOS

Good morning Toni,

Per our brief conversation this morning, the two petitioned substances under 3M petition are:

**Food Contact Substance 1**

FCS1 Name: Ammonium bis(N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, containing not more than 15% ammonium mono (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, where the alkyl group is more than 95% C8 and the salts have a fluorine content of 50.2% to 52.8% as determined on a solids basis

CAS Reg. No: FCS1 is mixture of ammonium bis(N-ethyl-2-perfluorooctylsulfonamido ethyl) phosphates and ammonium mono(N-ethyl-2-perfluorooctylsulfonamido ethyl) phosphates with less than 5 % chain lengths other than C8. Ammonium bis(N-ethyl-2-perfluorooctylsulfonamidoethyl) phosphates is assigned CAS Reg. No. 30381-98-7. ammonium mono(N-ethyl-2-perfluorooctylsulfonamido ethyl) phosphates is assigned CAS Reg. No.67969-69-1. (both are listed in Table 1 of 40 CFR §721.9582.)

**Food Contact Substance 2**

FCS2 Name: Perfluoroalkyl acrylate copolymer containing 35 to 40 weight percent fluorine, produced by the copolymerization of ethanaminium, N,N,N-trimethyl-2-[(2-methyl-1-oxo-2-propenyl)-oxy]-, chloride; 2-propenoic acid, 2-methyl-, oxiranylmethyl ester; 2-propenoic acid, 2-ethoxyethyl ester; and 2-propenoic acid, 2[[-(heptadecafluorooctyl)sulfonyl] methyl amino]ethyl ester

CAS Reg. No: 92265-81-1; the polymer does not appear to be is not listed in any of Tables 1-4 of 40 CFR §721.9582.

FCS2 is a polymer. The perfluoroalkyl containing monomer for synthesizing the polymer is 2-Propenoic acid, 2-[[[(1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluorooctyl)sulfonyl]methylamino]ethyl ester assigned CAS Reg. No. 25268-77-3; this is listed in Table 2

The main question: is the FCS 2 (polymer) the subject of reporting per EPA? Is FCS2 considered to be listed in Table 4 under "perfluoroalkyl derivative"?

If a foreign company wants to import FCS2 to the US, do they need to report the use of FCS2 to EPA?

The notice for 3M petition is likely published this week, and we will share a copy of the notice when available.  
Thanks for your help.

Sincerely,

Vanee Komolprasert, Ph.D., P.E.  
Consumer Safety Officer  
Division of Food Contact Notifications, HFS-275  
OFAS/CFSAN/FDA  
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**From:** Wolf, Joel [<mailto:Wolf.Joel@epa.gov>]  
**Sent:** Friday, April 08, 2016 10:55 AM  
**To:** Komolprasert, Vanee  
**Cc:** Krasnic, Toni  
**Subject:** RE: Questions on PFOS

Dear Vanee,

Thanks for the update on 3M and their petition seeking to remove use of two PFOS-related chemicals.

At the time of EPA's rulemaking on PFOS and PFOS-related chemicals under Toxic Substances Control Act (see [40 CFR §721.9582](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/long-chain-perfluorinated-chemicals-pfcs); also see <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/long-chain-perfluorinated-chemicals-pfcs> for links to final rules), 3M was the sole manufacturer of PFOS and PFOS-related chemicals that were regulated by EPA's significant new use rules (SNURs). After 3M's phaseout of those chemicals, some companies in China begun production of PFOS and PFOS-related chemicals, however, those chemicals cannot be imported into U.S. without first notifying EPA of intent to import by submitting a significant new use notice (SNUN) at least 90 days before doing so. The notification allows EPA to evaluate the intended use and to take appropriate action. To date, we have not received a SNUN on PFOS or any PFOS-related chemicals.

Hope this is helpful. If you have additional questions, please contact Toni Krasnic on my staff at 202-564-0984 or [krasnic.toni@epa.gov](mailto:krasnic.toni@epa.gov).

Best, Joel

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Joel Wolf  
Chief, Existing Chemicals Branch  
WJC East, Room 4121A  
202.564.0432, [wolf.joel@epa.gov](mailto:wolf.joel@epa.gov)

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**From:** Komolprasert, Vanee [<mailto:Vanee.Komolprasert@fda.hhs.gov>]  
**Sent:** Wednesday, April 06, 2016 12:21 PM  
**To:** Wolf, Joel <[Wolf.Joel@epa.gov](mailto:Wolf.Joel@epa.gov)>  
**Subject:** FW: Questions on PFOS  
**Importance:** High

Hi Joel,

Here is emails in communication with Jay Bassett (EPA in Atlanta, GA) whom I met at a meeting in Feb.  
Hope you can help answer our questions sent to Jay on 4/1/16, see below.

Thanks so much.

Sincerely,

Vanee Komolprasert, Ph.D., P.E.  
Consumer Safety Officer  
Division of Food Contact Notifications, HFS-275  
OFAS/CFSAN/FDA  
5100 Paint Branch Parkway  
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**From:** Komolprasert, Vanee  
**Sent:** Wednesday, April 06, 2016 11:38 AM  
**To:** 'Bassett, Jay'  
**Subject:** RE: Questions on PFOS  
**Importance:** High

Good morning Jay,

Any process on this? Is there a phone number that I can find out who involved in this matter?  
We have deadline to meet, so it is considered urgent.

Thanks again for your help.

Vanee

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**From:** Bassett, Jay [<mailto:Bassett.Jay@epa.gov>]  
**Sent:** Friday, April 01, 2016 10:17 AM  
**To:** Komolprasert, Vanee  
**Subject:** RE: Questions on PFOS

Vanee

This goes beyond my lane to address – I'll make a few calls and find the right person to answer your questions

Jay

Jay Bassett | Chief RCRA Programs and Materials Management  
404.562.8559 (w)

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**From:** Komolprasert, Vanee [<mailto:Vanee.Komolprasert@fda.hhs.gov>]  
**Sent:** Friday, April 01, 2016 9:42 AM  
**To:** Bassett, Jay <[Bassett.Jay@epa.gov](mailto:Bassett.Jay@epa.gov)>  
**Subject:** Questions on PFOS  
**Importance:** High

Good morning Jay,

How are you? Hope you do well. I have a few questions on PFOS and hope you are able to provide guidance and help.

We received a petition from the 3M company, seeking to remove use of two regulated chemicals derived from PFOS, and they claimed that they are the sole manufacturer of the PFOS in the US and overseas. If they stop making PFOS, then the two petitioned chemicals will not be available on the market for use. i.e., these two petitioned chemicals are no longer manufactured and its uses are considered to be abandoned. The 3M referenced the EPA Fact sheet on PFOS (March 2014) to support their claim.

In EPA Fact sheet (March 2014): [https://www.epa.gov/sites/production/files/2014-04/documents/factsheet\\_contaminant\\_pfos\\_pfoa\\_march2014.pdf](https://www.epa.gov/sites/production/files/2014-04/documents/factsheet_contaminant_pfos_pfoa_march2014.pdf), there is the following bullet on the second page, as follows.

"The 3M Company, the primary manufacturer of PFOS, completed a voluntary phase-out of PFOS production in 2002 (ATSDR 2009; 3M 2008)."

My questions are:

1. Does the statement suggest that the 3M be the sole manufacturer of PFOS in the US and overseas?
2. Does EPA know or have information that support the 3M is the sole manufacturer of PFOS in the US and overseas?
3. Does EPA have information of other (small, medium or large) manufacturers that may still produce PFOS (in the US and other countries)?

Any advice on this matter is appreciated.

Hope to hear from you soon.

Thanks.

Have a great weekend.

Best regards,

Vanee